DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

MICHELE OWEN, PH.D.
ZIKA LABORATORY TEAM LEAD September 21, 2016
EMERGENCY OPERATION CENTER
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
1600 CLIFTON RD. NE,
ATLANTA, GA 30333 US

Re: EUA160006/A002
Trade/Device Name: Trioplex Real-time RT-PCR Assay (Trioplex rRT-PCR)
Dated: August 22, 2016
Received: August 23, 2016

Dear Dr. Owen:

This is to notify you that your request for an update of the Instructions for Use of the Trioplex Real-time RT-PCR Assay (Trioplex rRT-PCR) to 1) include a large volume (up to 1.0 mL) nucleic acids extraction option for use with the authorized automated MagNA Pure 96 instrument for serum, urine, CSF, and amniotic fluid; 2) add two automated extraction instruments, the MagNA Pure Compact and the BioMerieux easyMAG instruments, for nucleic acids extraction from the appropriate clinical specimen types using the appropriate small and/or large volume extraction options per specimen type; and 3) add claims for detecting Zika virus, Dengue virus, and chikungunya virus RNAs in whole blood (EDTA) specimens has been granted.

Upon review, we concur that the analytical data and justifications submitted in EUA160006/A002 supports the addition of using the MagNA Pure 96 DNA and Viral NA Large Volume Kit on the automated MagNA Pure 96 instrument as a preferred large volume automated option for extraction of nucleic acids from clinical specimens for subsequent testing with the Trioplex rRT-PCR, and the inclusion of two additional automated extraction instruments, the MagNA Pure Compact and the BioMerieux easyMAG instruments, for nucleic acids extraction from the appropriate clinical specimen types using the appropriate small and/or large volume extraction options per specimen type in the Instruction for Use; the clinical and analytical testing data submitted in EUA160006/A002 supports the additional claims for detecting Zika virus, Dengue virus, and chikungunya virus RNAs in whole blood (EDTA) specimens.

We are also concurring with updates made to the Fact Sheets for the Trioplex rRT-PCR that reflect the addition whole blood (EDTA) as an authorized specimen type and the combining of the Patient and Pregnant Women Fact Sheets into one Fact Sheet for Patients.

By submitting this amendment for review by FDA, you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Trioplex Real-time RT-PCR Assay issued on March 17, 2016.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure